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TP

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/819,371	03/28/2001	Kohji Egawa	31508	4334
7590	04/21/2006		EXAMINER	CANELLA, KAREN A
John M. Collins HOVEY, WILLIAMS, TIMMONS & COLLINS Suite 400 2405 Grand Blvd. Kansas City, MO 64108			ART UNIT	PAPER NUMBER
			1643	
			DATE MAILED: 04/21/2006	

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/819,371	EGAWA, KOHJI	
	<b>Examiner</b>	<b>Art Unit</b>	
	Karen A. Canella	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) Claim(s) 60-72 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 60, 62-68 and 71 is/are allowed.
- 6) Claim(s) 69 and 70 is/are rejected.
- 7) Claim(s) 61 and 72 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: attachment.

### **DETAILED ACTION**

Claims 60, 61, 64-72 have been amended. Claims 60-72 are pending and under consideration.

Text of title 35, U.S. code not found in this action, can be found in a prior action.

Claims 61, 70 and 72 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 61 recites "cancer cell specific HLA-F antigen is obtained by expressing DNA comprising SEQ ID NO:3". Claim 70 recites "cancer cell specific HLA-F antigen is obtained by expressing DNA comprising SEQ ID NO:2". Claim 72 recites "cancer cell specific HLA-F antigen is obtained by expressing DNA comprising SEQ ID NO:1". Independent claims 60, 69 and 71 require the HLA-F antigen of EQ ID NO:6, SEQ ID NO:3 and SEQ ID NO:4. It is unclear how claims 61, 70 and 72 further limit claims 60, 69 and 71. The scope of claims 62, 70 and 72 appears to be the same as the scope of claims 60, 69 and 71, respectively.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (e) the invention was described in
  - (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent; or
  - (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 69 and 70 are rejected under 35 U.S.C. 102(e) as being anticipated by Morin et al (WO 01/75177, priority to April 3, 2000).

Art Unit: 1643

Claim 69 is drawn to a method of diagnosing a cancer that is non-specific to various organs comprising the steps of contacting a cancer cell specific HLA-F antigen comprising SEQ ID NO:5 with the body fluid of a subject and detecting the formation of an immune complex with antibodies in said body fluid.

Morin et al disclose the ovarian cancer antigen of SEQ ID NO:82 (page 13, line 19) which is identical to the instant SEQ ID NO:5. Morin et al teach (page 16, lines 1-7)

*In addition, since rapid tumor cell destruction often results in autoantibody generation, the ovarian tumor markers of the invention may be used in serological assays (e. g., an ELISA test of a subject's serum) to detect autoantibodies against ovarian tumor markers in a subject. Ovarian tumor marker polypeptide-specific autoantibody levels that are at least about 3-fold higher (and preferably at least 5-fold or 7-fold higher, most preferably at least 10-fold or 20-fold higher) than in a control sample are indicative of ovarian cancer.*

The disclosure of an ELISA test fulfills the specific embodiment requiring the application of a secondary antibody. The claim objective of diagnosing cancer that is non-specific to various organs fails to exclude the detection of ovarian cancer because the active method disclosed by Morin et al comprises the same steps as the instant method, the only difference being Morin et al did not disclose SEQ ID NO:82 as a "universal" cancer antigen. Further, Morin et al fulfills the specific limitation of claim 70 because the HLA-F antigen of claim 70 is obtained by the process of expressing the DNA of SEQ ID NO:2 and the M.P.E.P. (2113) states

***PRODUCT-BY-PROCESS CLAIMS ARE NOT LIMITED TO THE  
MANIPULATIONS OF THE RECITED STEPS, ONLY THE STRUCTURE  
IMPLIED BY THE STEPS***

Thus the cancer cell specific antigen obtained by expressing the DNA sequence of SEQ ID NO:2 is the same as the cancer cell antigen of SEQ ID NO:82 as disclosed by Morin et al.

Art Unit: 1643

All other rejections and objections as set forth in the previous Office action are withdrawn in light of applicants amendments.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 11 am to 10 pm, except Wed, Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella, Ph.D.

4/14/2006



KAREN A. CANELLA PH.D  
PRIMARY EXAMINER

GenCore version 5.1.7  
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## OM protein - protein search, using sw model

Run on: April 7, 2005, 12:59:38 : Search time 91.7626 Seconds

(without alignments) 1247.624 Million cell updates/sec

Perfect score: US-09-819-371-5

Sequence: 1 GSHSLRYFSTA VSRPGRGEP . . . . . QRYTCHVQHEGLPQLPLRW 274

Scoring table: Blosum62

Gapop 10.0 , Gapext 0.5

Searched: 1867569 seqs, 417829326 residues

Total number of hits satisfying chosen parameters: 1867569

Maximum DB seq length: 0

Maximum DB seq length: 2000000000

Post-processing: Minimum Match 0%

Maximum Match 100%

Listing first 45 summaries

Database : Published Applications AA Main:  
 1: /cgp2\_6/prodata/1/pubpa/us07\_PUBCOMB\_pep:  
 2: /cgp2\_6/prodata/1/pubpa/us08\_PUBCOMB\_pep:  
 3: /cgp2\_6/prodata/1/pubpa/us09\_PUBCOMB\_pep:  
 4: /cgp2\_6/prodata/1/pubpa/us10\_PUBCOMB\_pep:  
 5: /cgp2\_6/prodata/1/pubpa/us10\_PUBCOMB\_pep:  
 6: /cgp2\_6/prodata/1/pubpa/us11\_PUBCOMB\_pep:  
 Pred. No. is the number of results predicted by chance to have a score greater than or equal to the score of the result being printed, and is derived by analysis of the total score distribution.

## SUMMARIES

Result No. Score Query Match Length DB ID Description

1	1496	100.0	274	3	US-09-819-371-5	Sequence 5, Appli
2	1496	100.0	362	4	US-10-257-021-82	Sequence 82, Appli
3	1496	100.0	362	5	US-10-631-467-624	Sequence 624, App
4	1496	100.0	442	4	US-10-450-765A-187	Sequence 1887, App
5	1491	99.7	677	5	US-10-450-763-57085	Sequence 57085, A
6	1489	99.5	362	3	US-09-819-371-4	Sequence 4, Appli
7	1311	87.6	271	3	US-09-919-301-1431	Sequence 1431, Ap
8	1221	81.6	362	5	US-10-631-467-738	Sequence 728, App
9	1205	80.5	366	5	US-10-287-436A-101	Sequence 101, App
10	1205	80.5	366	5	US-10-287-436A-162	Sequence 162, App
11	1205	80.5	366	5	US-10-287-436A-1257	Sequence 1257, Ap
12	1205	80.5	366	5	US-10-287-436A-1267	Sequence 1267, Ap
13	1196	79.9	362	5	US-10-287-436A-120	Sequence 120, App
14	1196	79.9	362	5	US-10-287-436A-1260	Sequence 1260, Ap
15	1193	79.7	365	4	US-10-741-600-941	Sequence 941, App
16	1184	79.1	326	4	US-10-380-880-7	Sequence 7, Appli
17	1184	79.1	338	4	US-10-741-601-380	Sequence 380, App
18	1184	79.1	338	4	US-10-741-601-388	Sequence 388, App
19	1184	79.1	338	5	US-10-741-600-1134	Sequence 1134, Ap
20	1184	79.1	338	5	US-10-741-600-1138	Sequence 1138, Ap
21	1184	79.1	343	4	US-10-482-029-110	Sequence 110, App
22	1184	79.1	343	4	US-10-741-601-379	Sequence 379, App
23	1184	79.1	343	5	US-10-741-600-1139	Sequence 1139, Ap
24	1183	79.1	365	5	US-10-287-436A-179	Sequence 179, App
25	1183	79.1	365	4	US-10-287-436A-1268	Sequence 1268, App
26	1175	78.5	365	4	US-10-741-601-325	Sequence 325, App
27	1175	78.5	365	4	US-10-741-601-326	Sequence 326, App

## ALIGNMENTS

RESULT 1  
 US-09-819-371-5  
 ; sequence 5, Application US/09819371  
 ; Publication No. US20040053344A1  
 ; GENERAL INFORMATION:  
 ; APPLICANT: EGAWA, Kohji  
 ; TITLE OF INVENTION: Cancer Cell-Specific HLA-P Antigen and a Diagnostic Method of C  
 ; TITLE OF INVENTION: Using Thereof  
 ; FILE REFERENCE: 30815  
 ; CURRENT APPLICATION NUMBER: US/09/819,371  
 ; CURRENT FILING DATE: 2002-03-15  
 ; NUMBER OF SEQ ID NOS: 6  
 ; SOFTWARE: PatentIn version 3.0  
 ; SEQ ID NO 5  
 ; LENGTH: 274  
 ; TYPE: PRT  
 ; ORGANISM: Homo sapiens  
 US-09-819-371-5

Query Match 100.0%; Score 1496; DB 3; Length 274;  
 Best Local Similarity 100.0%; Pred. No. 1e-135; Mismatches 0; Indels 0; Gaps 0;  
 Matches 274; Conservative 0;

Qy 1 GSHSLRYFSTA VSRPGRGEP . . . . . QRYTCHVQHEGLPQLPLRW 60  
 Db 1 GSHSLRYFSTA VSRPGRGEP . . . . . QRYTCHVQHEGLPQLPLRW 60  
 Qy 61 EWTGTYAKANAOQTORVALNLRLRYNOSEASGHTLQGMNGCDMGPDRGLRLRGTGHAYDG 120  
 Db 61 EWTGTYAKANAOQTORVALNLRLRYNOSEASGHTLQGMNGCDMGPDRGLRLRGTGHAYDG 120  
 Qy 121 KDYISLNEDLRSTPAADTAQITQRFYEARBYABFRFTYLEGRCLBLRLYLENSKETLQ 180  
 Db 121 KDYISLNEDLRSTPAADTAQITQRFYEARBYABFRFTYLEGRCLBLRLYLENSKETLQ 180  
 Qy 181 RADDPKAHYAHHPSDHEATLRCWALGFPAEITLTWORDGERBTQDTTELVTETRPGDGT 240  
 Db 181 RADDPKAHYAHHPSDHEATLRCWALGFPAEITLTWORDGERBTQDTTELVTETRPGDGT 240  
 Qy 241 FQKHAAYVPSGEQRTCHVQHGLPQLLRW 274  
 Db 241 FQKHAAYVPSGEQRTCHVQHGLPQLLRW 274

RESULT 2  
 US-10-257-021-82-  
 ; sequence 52, Application US/10257021  
 ; Publication No. US20030211498A1  
 ; GENERAL INFORMATION:  
 ; APPLICANT: Morin, Patrice J.

1   APPLICANT: Sherman-Baust, Cheryl A.  
 1   APPLICANT: Pizer, Ellen S.  
 1   APPLICANT: Hough, Colleen D.  
 1   TITLE OF INVENTION: TUMOR MARKERS IN OVARIAN CANCER  
 1   FILE REFERENCE: 14014\_0369U2  
 1   CURRENT APPLICATION NUMBER: US/10/257, 021  
 1   PRIORITY APPLICATION NUMBER: PCT/US01/10947  
 1   PRIOR FILING DATE: 2001-04-03  
 1   PRIORITY APPLICATION NUMBER: 60/194,336  
 1   PRIOR FILING DATE: 2000-04-03  
 1   NUMBER OF SEQ ID NOS: 147  
 1   SOFTWARE: FastSEQ for Windows Version 4.0  
 1   SEQ ID NO: 82  
 1   LENGTH: 362  
 1   TYPE: PRT  
 1   ORGANISM: Homo sapiens  
 US-10-257-021-82

Query Match 100.0%; Score 1496; DB 4; Length 362;  
 Best Local Similarity 100.0%; Pred. No. 1.5e-135; Indels 0; Gaps 0;  
 Matches 274; Conservative 0; Mismatches 0; Del 0; Insert 0;  
 Gap 0;

Db 22 GSHSLRYFSTAVSRPGCGRGEPRTYIAVEYVDDTQFLRFDSDAAIPRMNPREPVEQEGPQYW 81  
 Qy 61 EWTGAKANQTDVALNLRLRRTYQSEASHTLQGMNGCDMGPDGRLLRGYHQHYDG 120  
 Db 82 EWTGAKANQTDVALNLRLRRTYQSEASHTLQGMNGCDMGPDGRLLRGYHQHYDG 141  
 Qy 121 KDYISLNEDELSWTAQDTVAQTQRTYEAEBRTYLEGBCLLRLRTYLEGELRTLQ 180  
 Db 142 KDYISLNEDELSWTAQDTVAQTQRTYEAEBRTYLEGBCLLRLRTYLEGELRTLQ 201  
 Qy 181 RADPPKAHVAAHHPISDHEATLRCWAALGYPAEITLTWORDGEQOTDTTELVTRPAGDGT 240  
 Db 202 RADPPKAHVAAHHPISDHEATLRCWAALGYPAEITLTWORDGEQOTDTTELVTRPAGDGT 261  
 Qy 241 FOKWAAYVVPSGEQRYTCHYQHEGLPQLLRW 274  
 Db 262 FOKWAAYVVPSGEQRYTCHYQHEGLPQLLRW 295

RESULT 4  
 US-10-408-765A-1887  
 ; Sequence 1887, Application No. US20040101874A1  
 ; GENERAL INFORMATION:  
 ;   APPLICANT: Ghosh, Soumitra S.  
 ;   APPLICANT: Zhang, Bing  
 ;   APPLICANT: Gibson, Bradford W.  
 ;   APPLICANT: Taylor, Steven W.  
 ;   APPLICANT: Glenn, Gary M.  
 ;   APPLICANT: Warnock, Dale E.  
 ; TITLE OF INVENTION: TARGETS FOR THERAPEUTIC INTERVENTION  
 ; IDENTIFIED IN THE MITOCHONDRIAL PROTEOME  
 ; FILE REFERENCE: 660088465  
 ; CURRENT APPLICATION NUMBER: US/10/408,765A  
 ; NUMBER OF SEQ ID NOS: 2003-04-04  
 ; SOFTWARE: FastSEQ for Windows Version 4.0  
 ; SEQ ID NO: 1887  
 ; LENGTH: 442  
 ; TYPE: PRT  
 ; ORGANISM: Homo sapiens  
 US-10-408-765A-1887

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 Matches 274; Conservative 0; Mismatches 0; Del 0; Insert 0;

Db 1 GSHSLRYFSTAVSRPGCGRGEPRTYIAVEYVDDTQPLRFDSDAAIPRMNPREPVEQEGPQYW 60  
 Qy 22 GSHSLRYFSTAVSRPGCGRGEPRTYIAVEYVDDTQPLRFDSDAAIPRMNPREPVEQEGPQYW 81  
 Db 61 EWTGAKANQTDVALNLRLRRTYQSEASHTLQGMNGCDMGPDGRLLRGYHQHYDG 120  
 Qy 82 EWTGAKANQTDVALNLRLRRTYQSEASHTLQGMNGCDMGPDGRLLRGYHQHYDG 141  
 Db 121 KDYISLNEDELSWTAQDTVAQTQRTYEAEBRTYLEGBCLLRLRTYLEGELRTLQ 180  
 Qy 142 KDYISLNEDELSWTAQDTVAQTQRTYEAEBRTYLEGBCLLRLRTYLEGELRTLQ 201  
 Db 181 RADPPKAHVAAHHPISDHEATLRCWAALGYPAEITLTWORDGEQOTDTTELVTRPAGDGT 240  
 Qy 202 RADPPKAHVAAHHPISDHEATLRCWAALGYPAEITLTWORDGEQOTDTTELVTRPAGDGT 261  
 Qy 241 FOKWAAYVVPSGEQRYTCHYQHEGLPQLLRW 274  
 Db 262 FOKWAAYVVPSGEQRYTCHYQHEGLPQLLRW 295

RESULT 5  
 US-10-450-763-57085  
 ; Sequence 57085, Application US/10450763  
 ; Publication No. US20050196754A1

Query Match 100.0%; Score 1496; DB 5; Length 362;  
 Best Local Similarity 100.0%; Pred. No. 1.5e-135; Indels 0; Gaps 0;  
 Matches 274; Conservative 0; Mismatches 0; Del 0; Insert 0;

Db 1 GSHSLRYFSTAVSRPGCGRGEPRTYIAVEYVDDTQPLRFDSDAAIPRMNPREPVEQEGPQYW 60